

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : A61B 17/36</p>	<p>A2</p>	<p>(11) International Publication Number: WO 95/13025 (43) International Publication Date: 18 May 1995 (18.05.95)</p>
<p>(21) International Application Number: PCT/GB94/02459 (22) International Filing Date: 9 November 1994 (09.11.94) (30) Priority Data: 9323111.6 9 November 1993 (09.11.93) GB (71) Applicant (for all designated States except US): SPEMBLY MEDICAL LIMITED [GB/GB]; Newbury Road, Andover, Hampshire SP10 4DR (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): VARNEY, Kelvin, John [GB/GB]; 1 Fairpiece Cottage, Wherwell, Andover, Hampshire SP11 7JD (GB). REEVES, Simon, Richard [GB/GB]; 2 Sandycroft, Church Road, Warsash, Southampton, Hampshire SO3 9AB (GB). (74) Agent: TURNER, James, Arthur; D. Young & Co., 21 New Fetter Lane, London EC4A 1DA (GB).</p>		<p>(81) Designated States: JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published Without international search report and to be republished upon receipt of that report.</p>
<p>(54) Title: CRYOSURGICAL PROBE</p> <div data-bbox="267 1155 1274 1438"></div> <p>(57) Abstract</p> <p>A cryosurgical probe comprises a probe head operable to be cooled by the expansion of a refrigerant gas within the probe head; a probe handle having means for precooling the refrigerant gas; and a flexible catheter linking the probe handle and the probe head, the catheter defining a channel for carrying precooled refrigerant gas from the probe handle to the probe head.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

CRYOSURGICAL PROBE

This invention relates to cryosurgical probes.

5 ~~Cryosurgical probes~~ employing a cooling element disposed at a distal end of a flexible catheter are used in the treatment of internal bodily organs such as the heart.

10 An example of a cryosurgical probe is disclosed in the British published patent application number GB-A-2 226 497. This probe comprises a handle portion, a flexible catheter and a probe head. The probe head may be cooled by the expansion of a refrigerant fluid within a cavity of the probe head.

15 In use, the probe head and catheter are inserted into, for example, a patient's blood vessel such as the femoral vein, and are steered so that the probe head occupies a position within the heart. High pressure refrigerant gas is then supplied through the catheter to the probe head to cause cryosurgical necrosis of small areas of the cardiac tissue which are responsible for malfunctions such as cardiac arrhythmias.

20 In contrast to, for example, rigid cryosurgical probes such as the probes described in GB-B-1457981 and GB-B-1108905, there are very severe constraints on the size of the probe head and the flexible catheter linking the probe head to the handle. These constraints tend to limit the maximum refrigerant flow to the probe head, and so the cooling efficiency of the probe head is particularly important.

25 The cooling efficiency of the probe head in this type of device is dependent on a number of factors, including the initial temperature of the high pressure refrigerant gas. For this reason, the probe head in GB-A-2 226 497 employs a heat exchanger comprising a spirally wound section of a gas delivery tube, to allow the exhaust (expanded) gas to cool the high pressure refrigerant. However, due to the size limitations of the probe head, this arrangement provides inefficient cooling of the refrigerant gas. The arrangement also leads to an undesirably bulky probe head. The size of the probe head limits the minimum vein diameter in which the probe can be used.

35 It is an aim of this invention to improve the cooling efficiency of a cryosurgical probe using a flexible catheter.

This invention provides a cryosurgical probe comprising: a probe

head operable to be cooled by the expansion of a refrigerant fluid within the probe head; a probe handle having means for precooling the refrigerant fluid; and a flexible catheter linking the probe handle and the probe head, the catheter defining a channel for carrying precooled refrigerant fluid from the probe handle to the probe head.

5 The invention addresses the above problems by providing precooling of the refrigerant fluid (e.g. a gas) at the probe handle, rather than at the probe head. This allows a much more powerful precooling arrangement (e.g. a dedicated refrigeration apparatus rather than merely a heat exchanger for heat transfer with the exhaust gases) 10 to be used, since the limits on the size of the probe handle are much less stringent than those relating to the probe head. The probe head and the flexible catheter can be made smaller, because there is no need to employ a heat exchanger at the probe head and because the increased efficiency of the probe head (using the pre-cooled refrigerant fluid) 15 means that a lower fluid flow is required to the probe head. This allows the probe to be used in narrower veins or in younger patients. Also, a heat insulating and flexible material (such as a plastics material) can be used (in place of commonly used stainless steel) to transport the high pressure refrigerant in the catheter and probe head. 20 since heat exchange at these points is no longer required.

In other words, this invention provides a cryosurgical catheter using a two-stage cooling process. The incoming refrigerant fluid is first pre-cooled by a relatively bulky but high-capacity refrigeration apparatus in the probe handle. This in turn makes the second stage of 25 cooling, namely the expansion of the fluid in the probe head, more efficient.

Although various different precooling arrangements could be used, such as passing the refrigerant fluid through a heat exchanger 30 surrounded by a cryogenic liquid such as liquid nitrogen, in an elegantly simple embodiment the same supply of refrigerant fluid is used (in different portions) for the precooling and for the probe head cooling. To this end, it is preferred that the probe handle comprises a conduit for carrying the refrigerant fluid to the flexible catheter, the conduit having an aperture such that a portion of the refrigerant 35 fluid is allowed to expand within the probe handle.

Preferably the portion of the refrigerant fluid expands into an

expansion chamber within the probe handle, the expansion chamber having an exhaust outlet communicating with an atmospheric air vent. This means that the fluid which passes to the probe tip is that portion which has not expanded within the handle.

5 In order to provide efficient heat exchange between the expanded fluid in the probe handle and the refrigerant fluid, it is preferred that the probe handle comprises means for directing refrigerant fluid, which has expanded through the aperture, along the outside of at least a part of the conduit, thereby allowing heat exchange between the
10 expanded gas and the refrigerant fluid within the conduit.

Preferably the means for directing comprises a helical vaned structure for directing the expanded fluid in a helical path along at least a part of the conduit.

15 In a preferred embodiment the means for directing are operable to direct the expanded fluid in an opposite direction to the flow of refrigerant fluid through the conduit. This provides for convenient exhaust of the expanded fluid (away from the catheter) and also ensures that the temperature gradients of both the incoming refrigerant and the fluid expanded within the handle are in the same direction (cooler
20 towards the catheter end of the handle).

For efficient heat transfer it is preferred that the conduit is a metal tube.

25 In order to provide a return path for exhaust gas from the probe head, and to avoid direct contact between the patient and the channel for carrying high pressure refrigerant (for safety reasons), it is preferred that the flexible catheter comprises an outer channel for carrying exhaust gas from the probe head to the probe handle and an inner channel, within the outer channel, for carrying refrigerant fluid from the probe handle to the probe head.

30 Since heat exchange is not required within the catheter, but flexibility of the catheter is desirable, it is preferred that the inner channel comprises a plastics tube. Plastics tubes are cheaper to manufacture and less likely to block by kinking than the previously used steel tubes.

35 Preferably the plastics tube is a polyamide tube having a thermal conductivity of less than 1 Watt per metre - Kelvin (W/mK).

It is preferred that the plastics tube has a rigidity modulus

(EI) of less than 20 Newtons per square metre (N/m^2).

In order that the temperature of the probe head can be monitored, it is preferred that the probe head comprises a temperature sensor for detecting the probe head temperature.

5 It is preferred that the probe comprises control means for controlling the flow of refrigerant fluid to the probe head in response to the probe head temperature. In this way a negative feedback arrangement can be used to control the probe head temperature to be substantially a desired value.

10 Preferably the control means is selectively operable, under user control:

(i) to prevent and vent the flow of refrigerant fluid to the probe head;

15 (ii) to control the flow of refrigerant fluid to the probe head to control the probe head temperature to be substantially 0° Celsius; and

20 (iii) to control the flow of refrigerant fluid to the probe head to control the probe head temperature to be cooled to a temperature below 0° Celsius, suitable for cryosurgical necrosis of a patient's tissue.

This arrangement allows a surgeon to cool a particular part of the patient's tissue to 0° Celsius, to cause the probe head to freeze to that tissue and to disable electrical activity within that tissue. If a malfunction such as a cardiac arrhythmia ceases, the surgeon can then

25 cause that tissue to be necrosed.

Preferably the control means comprises: means for detecting a sudden increase in the probe head temperature (warming); and means, responsive to a detection of a sudden increase in the probe head temperature, for preventing and venting the flow of refrigerant fluid

30 to the probe head. Since a sudden increase in temperature (e.g. an increase to at least a predetermined temperature) can indicate an increase in the fluid back pressure (e.g. caused by a blockage), it is safer to shut off and vent the fluid flow in these circumstances.

35 In order to assist a surgeon in correctly positioning the probe head on a required portion of tissue, it is preferred that the probe head comprises one or more electrodes for detecting electrical impulses generated by a patient's bodily tissue. Preferably means are provided

for displaying a visual indication of the electrical impulses.

In order to provide a coaxial cable arrangement for conducting the electrical signals, it is preferred that the flexible catheter comprises a strengthening electrically conductive braid for connecting one of the one or more electrodes to the probe handle.

In order to assist in steering the probe head in the region of the target tissue, it is preferred that the probe head is disposed at an angle with respect to the flexible catheter. Alternatively, a more complex steering system may be used, in which the flexible catheter comprises one or more control wires for linking the probe head to the probe handle, the one or more control wires being connected to the probe head such that longitudinal movement of the one or more control wires causes the orientation of the probe head to change with respect to the flexible catheter; and the probe handle comprises orientation control means, connected to the one or more control wires, for allowing a user to move longitudinally the one or more control wires.

The orientation control means could comprise, for example, slide controls connected to the control wires and mounted on the probe handle. However, in an advantageously simple embodiment the orientation control means comprises at least one rotatable crank connected to the one or more control wires.

Viewed from a second aspect this invention provides a cryosurgical probe comprising: a probe head operable to be cooled by the expansion of a refrigerant fluid within the probe head; a flexible catheter linking the probe handle and the probe head, the catheter defining a channel for carrying the refrigerant fluid from the probe handle to the probe head; means for detecting a sudden increase in the probe head temperature; and means, responsive to a detection of a sudden increase in the probe head temperature, for preventing and venting the flow of refrigerant fluid to the probe head.

Viewed from a third aspect this invention provides a cryosurgical probe control unit for controlling a cryosurgical probe having a probe head operable to be cooled by the expansion of a refrigerant fluid within the probe head, the unit comprising: means for supplying a refrigerant fluid to the probe head; means for detecting a sudden increase in the probe head temperature; and means, responsive to a detection of a sudden increase in the probe head temperature, for

preventing and venting the flow of refrigerant fluid to the probe head.

Viewed from a fourth aspect this invention provides a cryosurgical probe handle connectable via a flexible catheter to a probe head operable to be cooled by the expansion of a refrigerant fluid within the probe head, the handle comprising means for precooling the refrigerant fluid.

The invention will now be described by way of example with reference to the accompanying drawings, throughout which like parts are referred to by like references, and in which:

Figure 1 is a schematic diagram of a cryosurgical probe;

Figure 2 is a schematic diagram illustrating the cooling operation of a probe head;

Figure 3 is a schematic diagram illustrating the precooling operation of a probe handle;

Figure 4 is a schematic diagram illustrating a probe handle connected to a control apparatus;

Figure 5 is a schematic diagram illustrating steering of the probe head by torque control; and

Figure 6 is a schematic diagram of a two-axis steering mechanism.

Referring now to Figure 1, a cryosurgical probe comprises a probe handle 10, a probe head 20, and a flexible catheter 30 linking the probe handle and the probe head.

The cryosurgical probe shown in Figure 1 may be used in surgical procedures in which a patient's bodily tissue is locally cooled to such a degree that the tissue is locally destroyed. The cryosurgical probe has particular application to treatment of internal organs such as the human heart. In this case, the probe head 20 and the flexible catheter 30 are inserted into the femoral vein from a position in the patient's groin, and are passed through the patient's vein structure to reach the heart. Once the probe head 20 is in position in the patient's heart, the probe head can be cooled to destroy small portions of the heart tissue responsible for malfunctions of the heart such as arrhythmias.

The cooling of the probe head is performed using expansion of a refrigerant gas in accordance with the Joule-Thomson effect, described in the book 'Equilibrium Thermodynamics' (C J Adkins, Cambridge University Press, 1983). For this purpose, the refrigerant gas at a high pressure (e.g. 4×10^6 Pascals) is supplied to the probe handle 10

via an inlet tube 40, and exhaust (expanded) gas at a lower pressure is returned from the probe handle 10 by an exhaust tube 50.

The probe handle 10 comprises means for precooling the high pressure refrigerant gas to be used for cooling at the probe head.

5 This precooling can improve the cooling performance of the probe head. The means for precooling will be described in detail below.

The flexible catheter 30 has a diameter of nominally 3 mm (conventionally referred to as a '9 French catheter'). The outer wall of the catheter 30 is strengthened with a metal braid, which is also
10 used as an electrical conductor (see below).

Figure 2 is a schematic diagram illustrating the cooling operation of the probe head 20. In the probe head 20, high pressure refrigerant fluid is delivered through a narrow bore tube 60, and expands from the end 70 of the tube 60 into a larger exhaust cavity 80.
15 This causes local cooling of a rounded metal tip 90 of the probe head by the Joule-Thomson effect.

The rounded metal tip 90 of the probe head 20 provides a smooth leading surface for the probe head 20 as it is directed along a patient's blood vessels, and also allows effective heat conduction from
20 the patient's tissue in contact with the tip 90 to the expanded refrigerant gas in the probe head 20.

Figure 3 is a schematic diagram illustrating the precooling operation of the probe handle 10.

High pressure refrigerant gas received through the inlet tube 40 is passed through an axial conduit 100 in the probe handle 10 before
25 entering an axial refrigerant supply tube 110 in the catheter 30 (connected to the tube 60 in the probe head 20).

The refrigerant supply is a polyamide tube having a thermal conductivity of less than 1 Watt per metre - Kelvin (W/mK) and a
30 rigidity modulus (EI) of less than 20 Newtons per square metre (N/m²).

An aperture 120 in the conduit 100 allows a portion (about two thirds) of the refrigerant gas to expand into an expansion area 130 of the probe handle 10. As mentioned above, this causes the expanded refrigerant gas to cool by the Joule-Thomson effect. The cooled gas is
35 then directed by a helically-vaned heat exchanging structure 140 in a helical path around the conduit 100. This allows heat transfer from the high pressure refrigerant gas in the conduit 100 to the expanded

gas in the expansion region 130, thereby precooling the high pressure refrigerant gas in the conduit 100. In order to assist the heat transfer, the conduit 100 and the vaned heat exchanger 140 are fabricated from a good heat conducting material such as copper.

5 A second aperture 150 allows the refrigerant gas which has expanded through the aperture 120 to escape along the exhaust tube 50.

The portion of the high pressure refrigerant gas which does not expand through the aperture 120 passes into the refrigerant supply tube 110 in the flexible catheter 30, to be supplied to the probe head 20. Exhaust gas from the probe head 20 returns to the probe handle through
10 an exhaust return tube 160 which communicates with the exhaust cavity 80 in the probe head. This exhaust gas from the probe head 20 passes through apertures 170 into an outer region of the body of the probe handle 10, and from there into the exhaust tube 50.

15 Figure 4 is a schematic diagram illustrating the probe handle 10 connected to control apparatus 200, 210.

The control apparatus 200 attends to the control of the flow of high pressure refrigerant gas to the probe handle 10 and, ultimately, to the probe head 20. The apparatus 200 comprises a vessel 220
20 containing high pressure refrigerant gas and connected, via a flow valve 230, to the inlet tube 40. The exhaust tube 50 from the probe handle is connected to an atmospheric air vent 240 or scavenging system.

A thermocouple temperature sensor is provided in the probe head
25 20. An electrical signal from the thermocouple sensor is passed, via signal wires (not shown) within the flexible catheter 30 and the exhaust tube 50 to a temperature detector 250 within the control apparatus 200. An output electrical signal from the temperature detector 250 is passed in parallel to a high pass electrical filter 260
30 and a feedback temperature controller 270.

The high pass filter 260 detects a sudden increase in the temperature of the probe head 20 (e.g. an increase over a threshold tip temperature such as -65° Celsius). Such a sudden increase indicates a corresponding increase in the back pressure (exhaust pressure) of the
35 cooling operation in the probe head 20 and can therefore indicate a possible blockage in the exhaust return tube 160 or the exhaust tube 50. In this case, for safety reasons the flow of refrigerant gas to

200 applying a control signal to the flow valve 230. The refrigerant supply tube 110 is also vented by an atmospheric air vent (not shown).

5 The feedback temperature controller 270 responds to either a variable temperature control (to be set by a surgeon or other operator using the cryosurgical probe) or, as shown in Figure 4, to three possible temperature selections, namely 'Off', '0 Degrees' and 'Freeze'. In Figure 4, these selections are made by control buttons mounted on the probe handle 10. However, in other embodiments, the
10 temperature controls could be part of the control apparatus 200.

When the temperature control is set to 'Off', the flow of refrigerant gas to the probe handle 10 is shut off completely by means of a control signal from the feedback temperature controller 270 to the flow valve 230. The refrigerant supply tube 110 is also vented to an
15 atmospheric air vent (not shown).

When the temperature control is set to '0 Degrees', the feedback temperature controller 270 varies the flow of refrigerant gas to the probe handle 10 using negative feedback in order to maintain a probe head temperature of substantially 0° Celsius.

20 When the temperature control is set to 'Freeze', the feedback temperature controller 270 controls the flow valve 230 to open fully, thereby decreasing the probe head temperature to a temperature (for example, -30° Celsius to -70° Celsius) suitable for cryosurgical necrosis of the patient's bodily tissue.

25 The reason for the three stage temperature control in this embodiment is as follows. During, for example, a surgical operation to eliminate cardiac arrhythmia, it is necessary to destroy small parts of the heart tissue responsible for generating or transmitting spurious electrical signals within the heart which cause the arrhythmia.
30 However, it is important that incorrect parts of the heart tissue are not inadvertently destroyed.

In order to identify the correct portions of the tissue to be destroyed, the surgeon positions the probe head 20 at an approximately correct position within the heart, and then controls the probe head
35 temperature to be reduced to substantially 0° Celsius. This has two effects: the metal tip 90 of the probe head 20 is frozen to a particular portion of the tissue, and electrical activity in that

tissue is rendered inactive (although the tissue is not killed) by being cooled to the freezing point of water.

If the tissue to which the tip 90 is currently frozen is responsible for the cardiac arrhythmia, then cooling that tissue to 0° Celsius will cause the arrhythmia to be temporarily stopped. In this case, the surgeon can then operate the control to cause the probe head temperature to be reduced to a suitable temperature for cryosurgical necrosis of that area of tissue. The necrosis of the tissue is then performed without the probe head temperature rising above 0° Celsius. so that the tip 90 of the probe head 20 remains in contact with the same portion of tissue throughout the necrosis process.

If, however, cooling the probe head to 0° Celsius does not cause the arrhythmia to cease, the surgeon knows that he had not yet identified the correct portion of cardiac tissue to be necrosed. In this case, the cooling of the probe head is stopped and, when the tip 90 has thawed and been freed from the tissue to which it was frozen, another area of cardiac tissue can be tested by cooling to 0° Celsius.

The control apparatus 210 in Figure 4 comprises a signal amplifier 280 and a signal display 290. The signal amplifier 280 receives electrical impulses from electrodes disposed at the probe head 20 and amplifies those impulses for identification on the signal display 290. This provides a further aid to the surgeon to assist in correctly positioning the probe head 20 on the area of cardiac tissue to be destroyed.

Figure 5 is a schematic diagram illustrating steering of the probe head within the patient's blood vessels by torque control. In this embodiment, the probe head 20 is disposed at an angle to the flexible catheter 30. This means that axial rotation 300 of the flexible catheter 30 (for example by rotating the entire probe handle 10) causes a corresponding change 310 in the orientation of the probe head 20.

Figure 6 is a schematic diagram illustrating a two-axis steering mechanism for steering the probe head 20.

In Figure 6, two control wires 320, 330 are connected to a rotatable crank 340 forming part of the probe handle 10. The control wires 320, 330 pass along the flexible catheter 30 into the probe head 20 and are linked to opposite sides 350, 360 of the probe head 20.

This arrangement means that rotation of the crank 340 in, for example, a clockwise direction causes the control wire 320 to be pushed towards the probe head 20 and the control wire 330 to be pulled from the probe head 20. This in turn causes a downward movement 370 of the probe head 20.

This type of steering mechanism can be applied in two orthogonal directions, to provide a four-axis steering mechanism.

Figure 6 also illustrates the thermocouple 400 connected via signal wires 410 to the temperature detector 250 in the control apparatus 200. Sensing of electrical impulses at the probe head is provided by two electrodes, one of which is the probe head tip 90 and the other which 420 is an annular metal ring around the probe head 20. The probe head tip 90 is connected to the probe handle 10 by a metal braid which is also used for strengthening the flexible catheter 30. The electrode 420 is connected to the probe handle 10 by a signal wire 430. This arrangement is similar to a coaxial cable and provides screening of the signal wire 430.

In another embodiment, four or more electrodes (for example three annular electrodes plus the probe head tip 90) could be used.

CLAIMS

1. A cryosurgical probe comprising:
a probe head operable to be cooled by the expansion of a
5 refrigerant fluid within the probe head;
a probe handle having means for precooling the refrigerant fluid;
and
a flexible catheter linking the probe handle and the probe head,
the catheter defining a channel for carrying precooled refrigerant
10 fluid from the probe handle to the probe head.
2. A probe according to claim 1, in which the probe handle comprises
a conduit for carrying the refrigerant fluid to the flexible catheter,
the conduit having an aperture such that a portion of the refrigerant
15 fluid is allowed to expand within the probe handle.
3. A probe according to claim 2, in which the portion of the
refrigerant fluid expands into an expansion chamber within the probe
handle, the expansion chamber having an exhaust outlet communicating
20 with an atmospheric air vent.
4. A probe according to claim 2 or claim 3, in which the probe
handle comprises means for directing refrigerant fluid, which has
expanded through the aperture, along the outside of at least a part of
25 the conduit, thereby allowing heat exchange between the expanded fluid
and the refrigerant fluid within the conduit.
5. A probe according to claim 4, in which the means for directing
comprises a helical vaned structure for directing the expanded fluid in
30 a helical path along at least a part of the conduit.
6. A probe according to claim 4 or claim 5, in which the means for
directing are operable to direct the expanded fluid in an opposite
direction to the flow of refrigerant fluid through the conduit.
35
7. A probe according to any one of claims 2 to 6, in which the
conduit is a metal tube.

8. A probe according to any one of the preceding claims, in which the flexible catheter comprises an outer channel for carrying exhaust fluid from the probe head to the probe handle and an inner channel, within the outer channel, for carrying refrigerant fluid from the probe handle to the probe head.

9. A probe according to claim 8, in which the inner channel comprises a plastics tube.

10. A probe according to claim 9, in which the plastics tube is a polyamide tube having a thermal conductivity of less than 1 Watt per metre - Kelvin (W/mK).

11. A probe according to claim 9 or claim 10, in which the plastics tube has a rigidity modulus (EI) of less than 20 Newtons per square metre (N/m²).

12. A probe according to any one of the preceding claims, in which the probe head comprises a temperature sensor for detecting the probe head temperature.

13. A probe according to claim 12, comprising control means for controlling the flow of refrigerant fluid to the probe head in response to the probe head temperature.

14. A probe according to claim 13, in which the control means is selectively operable, under user control:

(i) to prevent and vent the flow of refrigerant fluid to the probe head;

(ii) to control the flow of refrigerant fluid to the probe head to control the probe head temperature to be substantially 0° Celsius; and

(iii) to control the flow of refrigerant fluid to the probe head to control the probe head temperature to be cooled to a temperature below 0° Celsius, suitable for cryosurgical necrosis of a patient's tissue.

15. A probe according to claim 13 or claim 14, in which the control means comprises:

means for detecting a sudden increase in the probe head temperature; and

5 means, responsive to a detection of a sudden increase in the probe head temperature, for preventing and venting the flow of refrigerant fluid to the probe head and for venting exhaust fluid from the probe head..

10 16. A probe according to any one of the preceding claims, in which the probe head comprises one or more electrodes for detecting electrical impulses generated by a patient's bodily tissue.

15 17. A probe according to claim 16, comprising means for displaying a visual indication of the electrical impulses.

20 18. A probe according to claim 16 or claim 17, in which the flexible catheter comprises a strengthening electrically conductive braid for connecting one of the one or more electrodes to the probe handle.

19. A probe according to any one of the preceding claims, in which the probe head is disposed at an angle with respect to the flexible catheter.

25 20. A probe according to any one of claims 1 to 18, in which:
the flexible catheter comprises one or more control wires for linking the probe head to the probe handle, the one or more control wires being connected to the probe head such that longitudinal movement of the one or more control wires causes the orientation of the probe
30 head to change with respect to the flexible catheter; and

the probe handle comprises orientation control means, connected to the one or more control wires, for allowing a user to move longitudinally the one or more control wires.

35 21. A probe according to claim 20, in which the orientation control means comprises at least one rotatable crank connected to the one or more control wires.

22. A cryosurgical probe comprising:

a probe head operable to be cooled by the expansion of a refrigerant fluid within the probe head;

5 a flexible catheter linking the probe handle and the probe head, the catheter defining a channel for carrying the refrigerant fluid from the probe handle to the probe head;

means for detecting a sudden increase in the probe head temperature; and

10 means, responsive to a detection of a sudden increase in the probe head temperature, for preventing and venting the flow of refrigerant fluid to the probe head.

23. A probe according to any one of the preceding claims, in which the refrigerant fluid is a refrigerant gas.

15

24. A cryosurgical probe control unit for controlling a cryosurgical probe having a probe head operable to be cooled by the expansion of a refrigerant fluid within the probe head, the unit comprising:

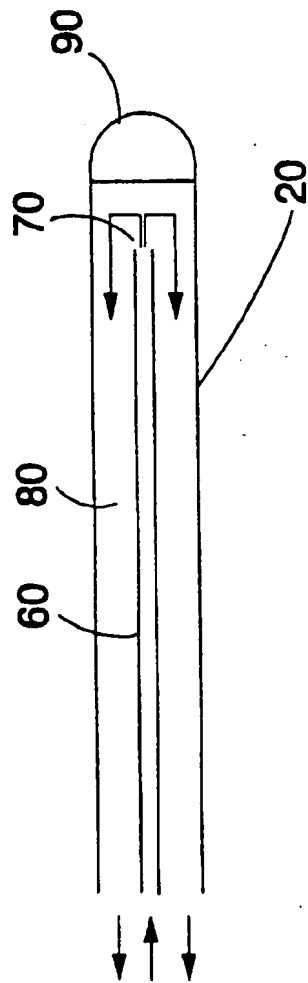
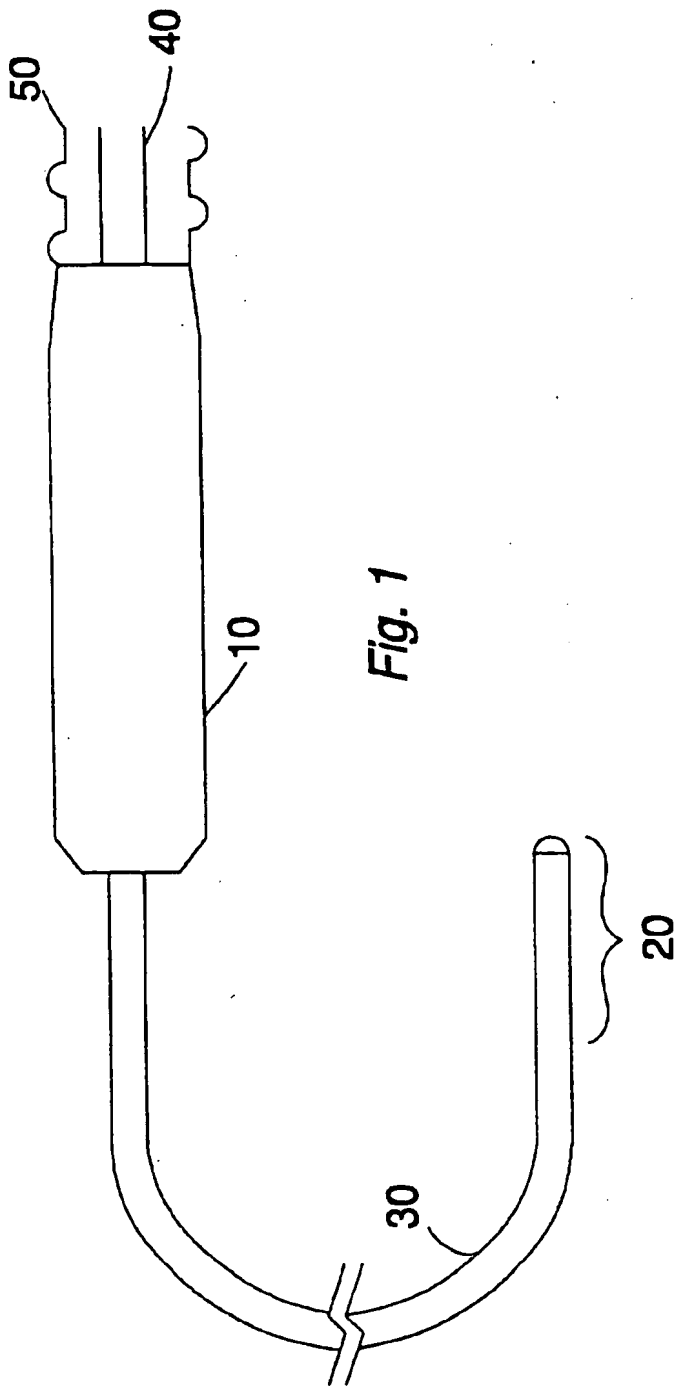
means for supplying a refrigerant fluid to the probe head;

20 means for detecting a sudden increase in the probe head temperature; and

means, responsive to a detection of a sudden increase in the probe head temperature, for preventing and venting the flow of refrigerant fluid to the probe head.

25

25. A cryosurgical probe handle connectable via a flexible catheter to a probe head operable to be cooled by the expansion of a refrigerant fluid within the probe head, the handle comprising means for precooling the refrigerant fluid.



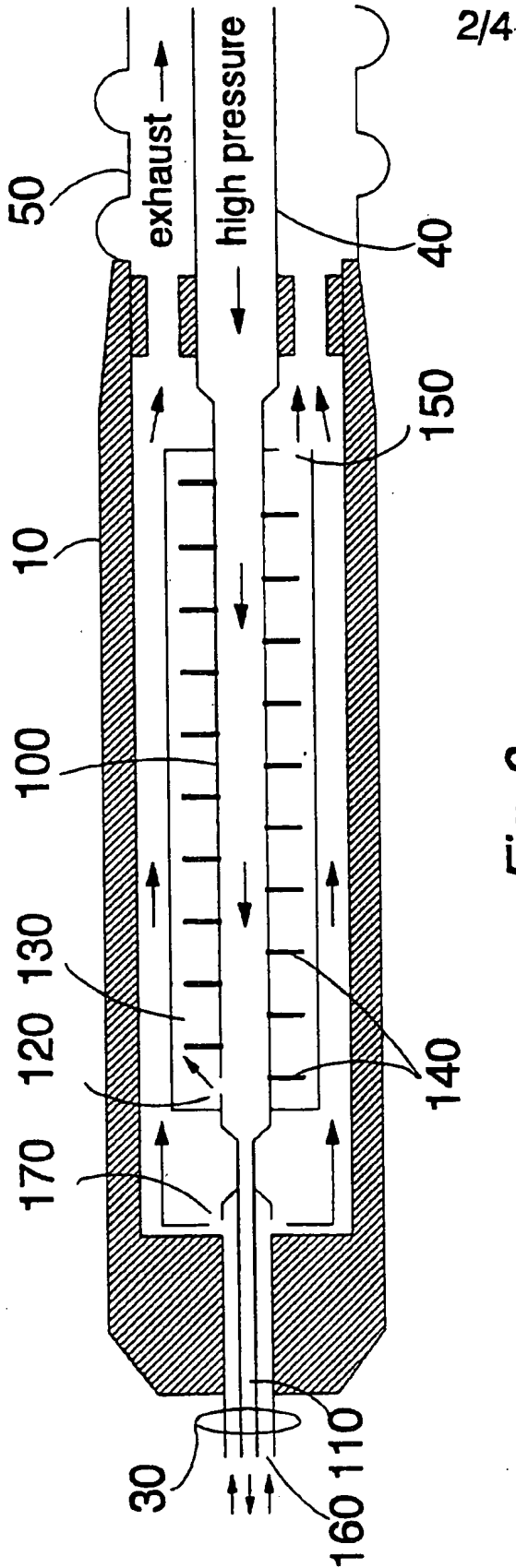


Fig. 3

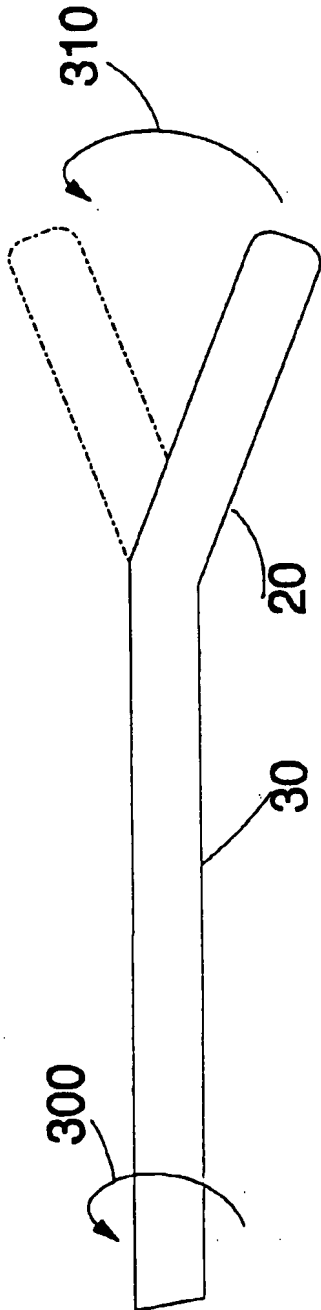


Fig. 5

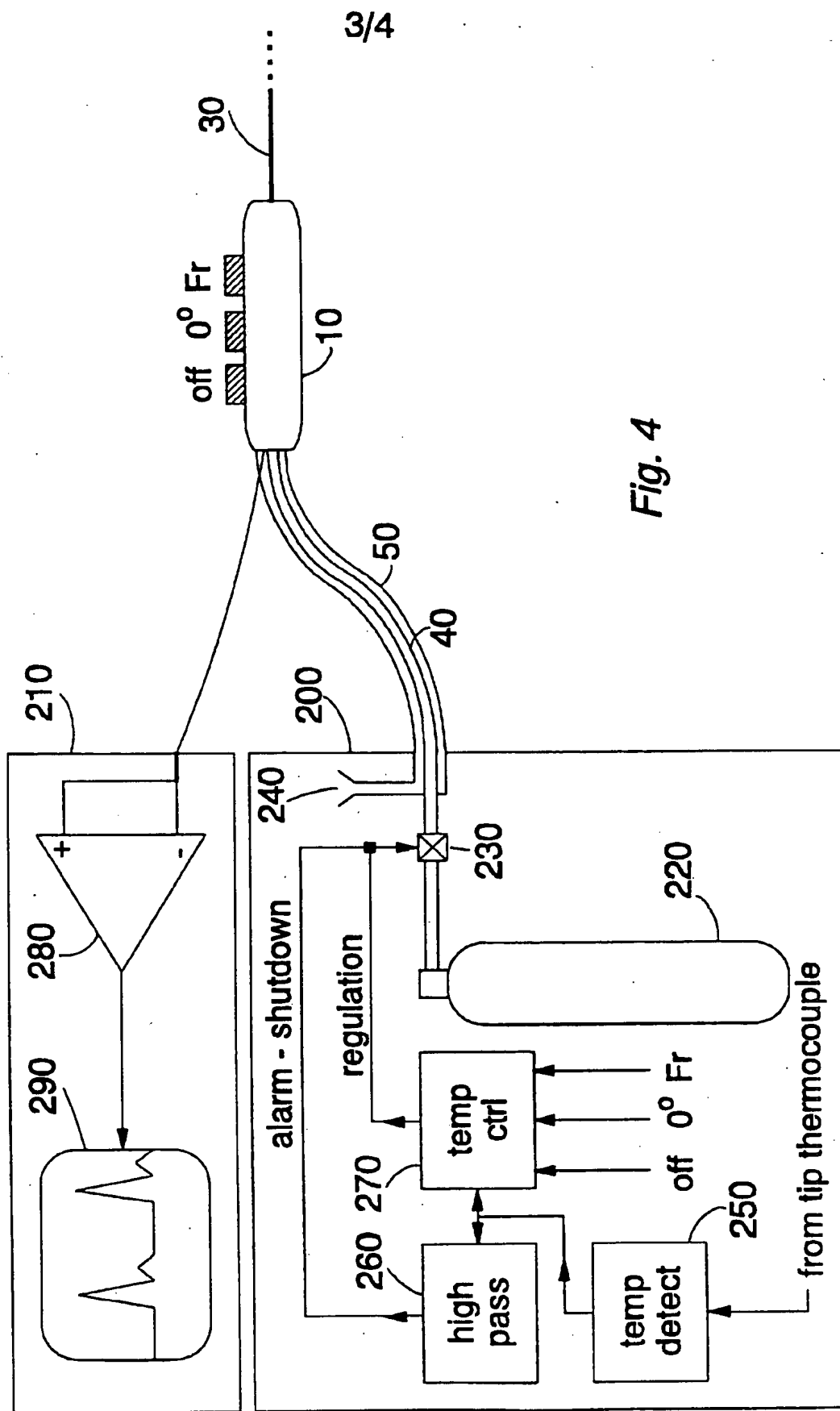


Fig. 4

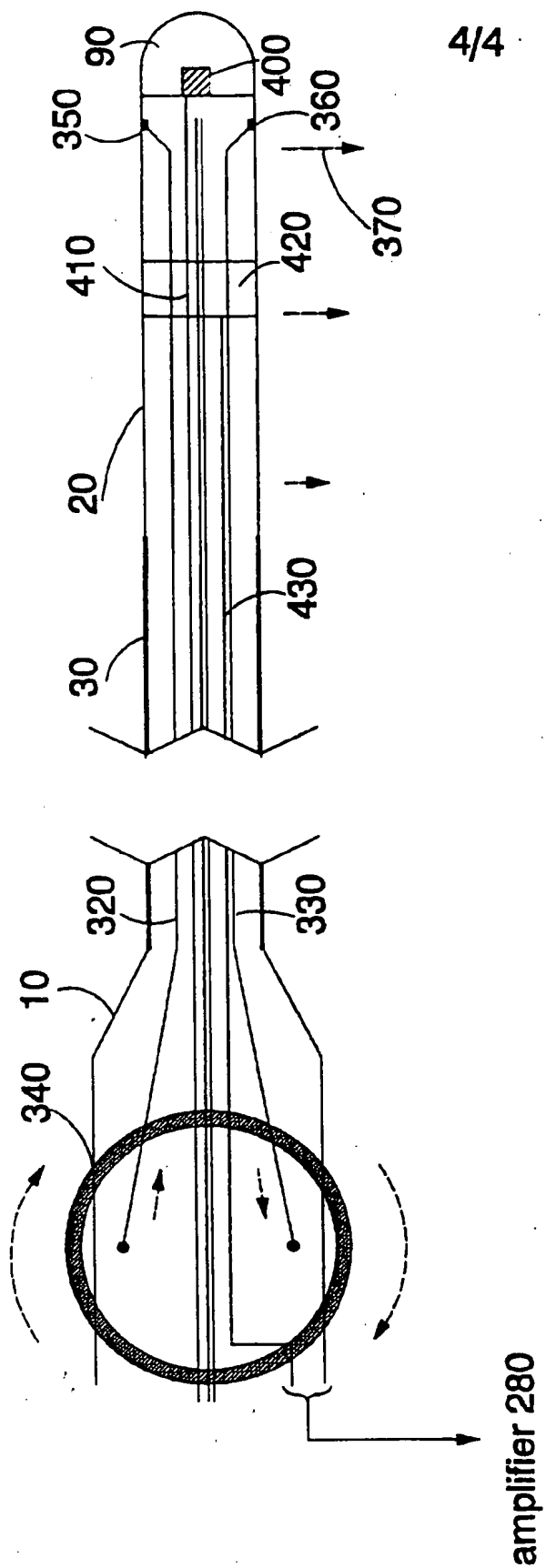


Fig. 6

PCT

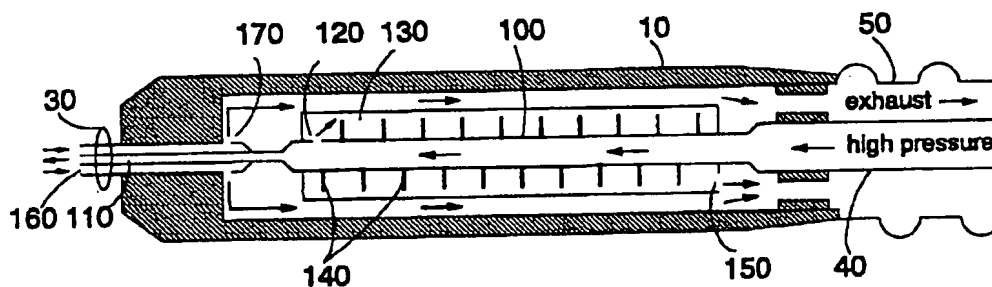
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/36		(11) International Publication Number: WO 95/13025
A3		(43) International Publication Date: 18 May 1995 (18.05.95)
(21) International Application Number: PCT/GB94/02459		(81) Designated States: JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: 9 November 1994 (09.11.94)		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(30) Priority Data: 9323111.6 9 November 1993 (09.11.93) GB		(88) Date of publication of the international search report: 13 July 1995 (13.07.95)
(71) Applicant (for all designated States except US): SPEMBLY MEDICAL LIMITED [GB/GB]; Newbury Road, Andover, Hampshire SP10 4DR (GB).		
(72) Inventors; and (75) Inventors/Applicants (for US only): VARNEY, Kelvin, John [GB/GB]; 1 Fairpiece Cottage, Wherwell, Andover, Hampshire SP11 7JD (GB). REEVES, Simon, Richard, [GB/GB]; 2 Sandycroft, Church Road, Warsash, Southampton, Hampshire SO3 9AB (GB).		
(74) Agent: TURNER, James, Arthur, D. Young & Co., 21 New Fetter Lane, London EC4A 1DA (GB).		

(54) Title: CRYOSURGICAL PROBE



(57) Abstract

A cryosurgical probe comprises a probe head operable to be cooled by the expansion of a refrigerant gas within the probe head; a probe handle having means for precooling the refrigerant gas; and a flexible catheter linking the probe handle and the probe head, the catheter defining a channel for carrying precooled refrigerant gas from the probe handle to the probe head.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TC	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

INTERNATIONAL SEARCH REPORT

Intern al Application No

PCT/GB 94/02459

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B F25B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB,A,2 226 497 (SPEMBLY MEDICAL LTD) 4 July 1990 cited in the application	1,25
Y	see claims 1,6	22-24
Y	GB,A,2 026 324 (BRACCO) 6 February 1980 see page 2, line 12 - line 17 see page 3, line 9 - line 14	22-24
A	US,A,3 630 203 (SELLINGER) 28 December 1971 see column 3, line 8 - line 12	1,25
A	EP,A,0 173 599 (L'AIR LIQUIDE) 5 March 1986	

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"A" document member of the same patent family

Date of the actual completion of the international search

31 May 1995

Date of mailing of the international search report

15.06.95

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Glas, J

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB94/02459

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims 1-21, 23, 25 : Cryosurgical probe with means in handle for precooling refrigerant fluid.
 2. Claims 22 and 24 : Cryosurgical probe with means for detecting a sudden increase in the probe head temperature and a control unit.
1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
 2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
 3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
 4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 94/02459

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB-A-2226497	04-07-90	US-A- 5078713	07-01-92
GB-A-2026324	06-02-80	DE-A- 2925270	10-01-80
		FR-A, B 2431854	22-02-80
		US-A- 4280499	28-07-81
US-A-3630203	28-12-71	GB-A- 1332181	03-10-73
EP-A-0173599	05-03-86	FR-A- 2568357	31-01-86
		DE-A- 3564735	06-10-88